In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-1116V
Filed: June 19, 2018
UNPUBLISHED

BEVERLY TOWNE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Fact Hearing; Findings of Fact; Onset; Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Verne E. Paradie, Jr., Paradie, Sherman, et al., Lewiston, ME, for petitioner.
Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for respondent.

FACT RULING[1]

Dorsey, Chief Special Master:

On September 9, 2016, Dr. Beverly Towne ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleges that she suffered left shoulder injuries caused by a Tetanus Diphtheria acellular Pertussis ("Tdap") vaccine she received on December 23, 2015. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed below, the undersigned finds that the onset of petitioner's left shoulder injuries was within 48 hours of her December 23, 2015 Tdap vaccination.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History Prior to Hearing

On September 8, 2016, Dr. Towne filed her petition and medical records marked as exhibits 1-3. (ECF No. 1.) On January 26, 2017, she filed exhibits 4-9 with a Statement of Completion. (ECF Nos.11, 13.)

On May 1, 2017, respondent filed a status report stating that medical personnel at the Division of Injury Compensation at the Department of Health and Human Services had completed a preliminary review of petitioner's claim and determined that "petitioner's symptoms [did] not appear to be within a feasible timeframe to infer a causal relationship with the vaccination." (ECF No. 17). Respondent also noted that when petitioner first reported her shoulder pain, approximately 19 weeks after vaccination, petitioner advised that it could be related to her exercises involving kettle bells. *Id*. Respondent proposed filing his report pursuant to Vaccine Rule 4(c) within 60 days. This request was granted. (*See* Non-PDF Order dated 05/02/2017).

On July 6, 2017, respondent filed his Rule 4(c) Report. (ECF No. 20.) Respondent recommended against awarding compensation to petitioner in this case, arguing, *inter alia*, that the record is insufficient to substantiate that the onset of petitioner's left shoulder symptoms began within forty-eight hours of vaccination. *Id*. at 3. Respondent reiterated her argument that petitioner first reported her shoulder symptomatology to a medical professional more than four months after vaccination, and even then she thought it may be related to kettle ball exercises. *Id.* citing Pet. Ex. 1 at 3-6. Respondent states that when petitioner ultimately did associate her pain with vaccination, the record is deficient in demonstrating that the onset was specifically within 48 hours and as such, "the current record does not establish by preponderant evidence that petitioner developed SIRVA as a result of her December 23, 2015 Tdap vaccination." *Id.* Respondent argues that the Vaccine Act prohibits a finding of entitlement "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." *Id.;* 42 U.S.C. § 300aa-13(a)(1).

Thereafter, the undersigned issued an order directing petitioner to file affidavits from any fact witnesses that would be able to support her position regarding the onset of her shoulder injury. (ECF No. 21). On October 23, 2017, petitioner filed the affidavit of the nurse who administered the vaccination, as well as an affidavit from the doctor for whom she was employed. *See* Pet. Exs. 10-11 (ECF Nos. 22-23).

On November 14, 2017, the parties filed a joint status report stating that they have been unable to resolve the matter and requested a fact hearing. On January 11, 2018, a status conference was held by the staff attorney managing this case and a fact hearing was scheduled. (ECF No. 26.) In preparation for the fact hearing, petitioner filed a pre-hearing submission. (ECF No. 28). Respondent filed no additional pre-hearing submissions.

II. Fact Hearing and Ruling

A fact hearing was held in Washington, D.C., on May 1, 2018. Dr. Towne was the sole witness and she appeared in-person with her attorney. At the conclusion of the hearing, the undersigned informed the parties that she intended to issue a ruling from the bench. The parties consented. The undersigned stated that her ruling would

resolve whether the onset of petitioner's symptoms occurred within 48 hours of vaccination.

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

> A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Id.; see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

With these factors in mind, the undersigned made the following preliminary findings of fact:

> [A]s I understand the Rule 4 in this case that . . . one of the issues in the case is onset, and that is whether or not Dr. Towne experienced the onset within 48 hours as required by the Table. After having reviewed all of the exhibits, the medical records, the affidavits of the witnesses and after hearing Dr. Towne's testimony today, I find that onset of her pain occurred within the specified time frame of less than or equal to 48 hours.
>
> My findings are based on a number of key pieces of evidence, including Dr. Towne's affidavit and her testimony here today; the affidavit of the nurse who administered the vaccine; as well as the affidavit of the physician she worked for who was also her PCP, Dr. Brian Knighton; the history documented by Dr. Knighton on May 6th, 2016 that Dr. Towne had left shoulder pain which initially began four to five months earlier; the history by Dr. Knighton when he documented that the Petitioner attributed the pain to getting a DTaP vaccination on 12/23/2015 when he notes she developed deltoid pain after the injection, since then she has had varying degrees of shoulder pain; as well as the evaluation by Dr. Sara Shubert on June 8th, 2016, when she documented that

petitioner also developed pain in the deltoid and lateral shoulder which persisted up until the current time after the Tdap injection.

Moreover, the initial physical therapy evaluation performed by Denise Bluhm, physical therapist, on June 27th, 2006, notes that Dr. Towne received a tetanus shot in her left shoulder December 2015, and the day after the injection had significant left upper trapezius and neck pain, which was still present after one week. It is also noted on the MRI report dated June 12th, 2016, that Petitioner's symptoms started 12/'15 at the time of the Tdap injection. Thus, I find that petitioner's pain began within 48 hours of the vaccine.

As for Dr. Towne's delay in seeking treatment until May of 2016, I find the reasons for her delay set forth in her affidavit and her testimony here today to be credible and reasonable. Specifically, because Dr. Towne is a physician, and it is typical for many medical professionals to self-treat or seek out informal advice about their own medical ailments, they often wait before seeking formal medical treatment. That is what I find happened in these circumstances, and I find the delay in seeking treatment to be reasonable given the facts and circumstances of this case. That is the end of my ruling.

Transcript at 46-48.

III. Conclusion

In light of all of the above, and in view of the submitted evidence, including the medical records, credible witness testimony, and findings of fact, the undersigned finds that the onset of petitioner's right shoulder injuries was within 48 hours of her December 23, 2015 Tdap vaccination.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master